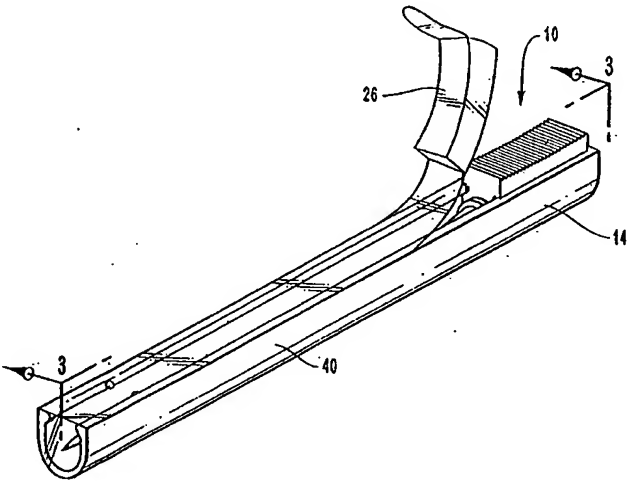


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(21) International Application Number: PCT/US99/14472 (22) International Filing Date: 25 June 1999 (25.06.99) (30) Priority Data: 09/112,251 8 July 1998 (08.07.98) US (71) Applicant: BECTON DICKINSON AND COMPANY [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US). (72) Inventors: SONDEREGGER, Ralph, L.; 1671 West 1440 North, Farmington, UT 84025 (US). HOWELL, Glade, H.; 1202 East 11000 South, Sandy, UT 84094 (US). (74) Agent: SERVILLA, Scott, S.; Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).		(81) Designated States: AU, BR, CA, CN, IN, JP, MX, SG, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: SEALABLE SAFETY CATHETER HAVING A COMBINATION NEEDLE RETRACTION CHAMBER AND NEEDLE COVER  (57) Abstract <p>A sealable safety catheter assembly with a needle retraction chamber doubling as a needle cover is provided. A needle hub assembly with an attached needle and associated catheter is contained within a housing of the needle retraction chamber. The needle hub assembly is at least partially accessible through a slot extending along the longitudinal axis of the housing of the needle retraction chamber. The needle hub assembly is also movable from a retracted position to an extended position with respect to the housing of the needle retraction chamber, and a mechanism for alternatively latching the needle hub assembly in a retracted or extended position is provided. Finally, a seal encloses the space within the needle retraction chamber around the needle and catheter when the needle is in the retracted position, thereby permitting the needle and catheter to be kept in a sterile environment prior to use and eliminating the need for a separate needle cover.</p>		

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**SEALABLE SAFETY CATHETER HAVING A COMBINATION
NEEDLE RETRACTION CHAMBER AND NEEDLE COVER**

BACKGROUND

1. The Field of the Invention

5 The present invention relates generally to the field of medical catheters. More specifically, the present invention relates to a sealable safety catheter with a needle retraction chamber that doubles as the needle cover. A seal permits the needle and catheter to be maintained in a sterile environment within the needle retraction chamber without additional packaging.

10 2. Technical Background

 During medical treatment, patients often require medication, blood, or fluids. The most efficient way of administering these substances is by depositing them directly into the patient's blood stream where the circulatory system quickly directs the substance to the target tissue or organ. Thus, vascular catheters for infusion of fluids, blood, and medications into patients are
15 among the most commonly used medical devices. The insertion of a vascular catheter allows repeated or continuous access to the circulatory system of a patient. Vascular catheters are generally inserted into the extremities of a patient and fluids, blood, and medications are provided to the patient through such catheters.

 Catheters of this type are generally inserted into a vein or artery by means of an introducer
20 needle. In one common configuration, the catheter is initially placed over the needle. The needle, with the catheter located over the needle, is inserted into the patient until the desired vein or artery is located. Once the needle and catheter are properly located in the vein or artery, the

5 needle is withdrawn from the catheter and discarded. The catheter remains in the vein or artery to provide access to the circulatory system of the patient without repeated needle punctures.

 It will be appreciated that after withdrawal of the needle, the needle is contaminated with the patient's blood and any blood borne diseases the patient may carry, such as HIV or hepatitis. Exposed needles, therefore, pose a health hazard to clinicians and other patients, and it is
10 important to minimize the risk of exposure to technicians who use vascular catheters.

 Catheters are known in the art that provide a needle retraction chamber in order to minimize the risk of exposure. Many devices have insertion needles that retract automatically or semiautomatically after use. However, prior to use, these needles are not contained within the needle retraction chamber. Rather, the catheters are packaged with the needle extending from the
15 chamber, ready for use. The needle is retracted into a needle retraction chamber only following use of the device. Such devices require a separate detachable needle cover for shielding the needle before use. However, separate detachable needle covers would likely be insufficient to maintain needle and catheter sterility prior to use. Thus, these devices require the entire catheter to be packaged in order to maintain sterility. Also, an extra manufacturing step is required to produce
20 the separate detachable needle cover.

 Other catheters are known in the art that are both retractable and extendable. One such device includes a housing and a hub with an attached needle. The hub is movable with respect to the housing and is capable of being locked in either an extended or retracted position. The device further includes a plunger that extends from the proximal end of the housing. The plunger
25 facilitates the movement of the hub, needle, and catheter into an extended position. However, because the plunger configuration provides a passageway for ambient air into the housing, the

5 entire device must be packaged in order to achieve and maintain sterility prior to use.

 Thus, it would be an advancement in the art to eliminate the need for a detachable needle cover and provide a safety catheter with a needle retraction chamber doubling as the needle cover. Also, because vascular catheters are so common in medical treatment, simplification of the required packaging for maintaining a sterile needle and catheter would be important in controlling
10 the costs of catheters. Consequently, it would be a further advancement in the art to provide a safety catheter where the needle and catheter may be kept sterile through the use of a simple seal. More particularly, it would be an advancement in the art to provide a seal that would reduce the relatively elaborate packaging required in the prior art.

15 BRIEF SUMMARY AND OBJECTS OF THE INVENTION

 The present invention provides a sealable safety catheter assembly which uses a needle retraction chamber as a cover. The invention includes, but is not limited to catheters less than 3 inches in length. The needle retraction chamber has a housing with an interior cavity and a distal and proximal end. A needle hub assembly is contained within this housing and is movable with
20 respect to the housing. More particularly, the needle hub assembly is capable of sliding between the distal and proximal ends of the housing.

 The needle hub assembly has a needle mounted on it such that the tip of the needle extends towards the distal end of the housing. The needle may be positioned within the housing, or it may be moved via the needle hub assembly and positioned such that the needle protrudes out of the
25 housing. In other words, the needle may be entirely extended from the distal end of the housing for insertion in a patient, or it may be entirely retracted within the housing before and after use.

5 A catheter is associated with the needle hub assembly and with the needle. The catheter may be contained within the needle, or it may rest on top of the needle and needle hub assembly. Preferably, the catheter rests on top of both the needle and needle hub assembly such that the needle is substantially contained within the catheter and only the tip of the needle protrudes from the catheter. Consequently, the needle and catheter may be simultaneously inserted into the
10 patient and the needle alone may be removed. The catheter is left partially inserted in the patient in order to administer medication, blood, or fluids.

 The present invention provides a mechanism for alternatively latching the needle hub assembly in a retracted or extended position. The needle must be held in an extended position to permit insertion of the needle and catheter into the patient without the needle hub assembly
15 retracting back into the housing. Furthermore, the needle should be capable of being held securely in a retracted position in order to prevent accidental exposure to the needle. The present invention provides that the needle, via the needle hub assembly, may be either securely extended from the housing, or alternatively secured within the housing. Specific mechanisms for alternatively latching the needle hub assembly are discussed below.

20 In one embodiment, there is a slot extending along the longitudinal axis of the housing of the needle retraction chamber. The needle hub assembly is at least partially accessible through this slot. Because the needle hub assembly is accessible, a user can directly move the needle hub assembly with respect to the housing of the needle retraction chamber. Some preferred embodiments also include a thumb-tab rigidly attached to, or integral with the needle hub
25 assembly. The thumb-tab extends from the interior cavity of the housing through the slot of the housing, and facilitates the movement of the needle hub assembly with respect to the housing.

5 Furthermore, the needle hub assembly may be prevented from passing out the distal end of the housing of the needle retraction chamber by a small, rigid shelf. The shelf is attached to the distal end of the interior cavity of the housing and physically blocks the passage of the needle hub assembly from the distal end of the housing. As a result, the needle cannot be removed from an intact device.

10 In one embodiment, a sealable safety catheter with the foregoing features is provided, but the mechanism for alternatively latching the needle hub assembly in a retracted or extended position includes at least one distal recess in the housing, at least one proximal recess in the housing, and at least one nub attached to the needle hub assembly. The nub(s) comprise small protrusions on the needle hub assembly that are capable of alternatively engaging with the distal
15 and proximal recesses, thus securing the needle hub assembly alternatively in either a retracted or extended position. The nub-recess engagement is secure enough to permit needle and catheter insertion into a patient without needle retraction, yet flexible enough to allow disengagement by jostling the needle hub assembly, e.g., via the thumb-tab.

In another embodiment, the mechanism for alternatively latching the needle hub assembly
20 includes openings in the distal and proximal ends of the housing of the needle retraction chamber and a spring-biased protrusion on the needle hub assembly. The spring-biased protrusion may be alternatively engaged in the distal or the proximal opening. Thus, the needle hub assembly may be secured in a retracted or extended position. Once engaged in either opening, the spring-biased protrusion is accessible from the outside of the housing. The protrusion may be manually pushed
25 in, releasing the engagement, and the needle hub assembly may then be moved to the alternative position.

5 Prior to use, when the needle is in the retracted position, a seal is removably attached to the needle retraction chamber such that the needle and catheter are sealed in a defined space within the housing of the needle retraction chamber. Thus, the needle and catheter may be kept sterile without further packaging. For certain embodiments, the seal covers the longitudinal slot in the housing as well as the distal end of the housing. For embodiments having a spring-biased
10 protrusion and openings, the seal covers the openings in addition to the longitudinal slot in the housing and the distal end of the housing. Preferably, the seal is plastic or paper, and is attached to the needle retraction chamber with adhesive. Alternatively, the seal may be a rigid cap capable of snapping on and off the needle retraction chamber.

 These and other objects of the invention will become more fully apparent by examination
15 of the following description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

 A more particular description of the invention briefly described above will be rendered by reference to the appended drawings. Understanding that these drawings only provide information
20 concerning typical embodiments of the invention and are not therefore to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings, in which:

 Figure 1 is a perspective view of the safety catheter of the present invention showing the introduction of a catheter into the arm of a patient.

25 Figure 2 is a perspective view of the safety catheter with the seal being removed.

 Figure 3 is a longitudinal cross sectional view of the safety catheter in a retracted position

5 prior to use, showing a nub engaged in a proximal recess.

Figure 4 is a longitudinal cross sectional view of the safety catheter in an extended position ready for use, showing a nub engaged in a distal recess.

Figure 5 is a longitudinal cross sectional view of the safety catheter in a retracted position following use, showing a nub engaged in a proximal recess and the catheter freed from the device.

10 Figure 6 is a cross sectional view across line 6-6 of Figure 4.

Figure 7 is a longitudinal cross sectional view of the safety catheter secured in a retracted position prior to use, showing openings in the distal and proximal ends of the housing of the needle retraction chamber, and a spring-biased protrusion on the needle hub assembly engaged in the proximal opening.

15 Figure 8 is a longitudinal cross sectional view of the safety catheter showing the needle hub assembly secured in an extended position ready for use, where the spring-biased protrusion on the needle hub assembly is engaged in the distal opening, and also showing the subsequent retraction of the needle hub assembly within the housing of the needle retraction chamber in phantom lines.

20 Figure 9 is a longitudinal cross sectional view of the safety catheter secured in a retracted position following use, showing a freed catheter and the spring-biased protrusion on the needle hub assembly engaged in the proximal opening.

DETAILED DESCRIPTION

25 Reference is now made to the figures wherein like parts are referred to by like numerals throughout. The present invention is a safety catheter 10, shown in use in Figure 1. The invention

5 is used for introducing a catheter 12 into a patient so that medication, blood, and fluids may be deposited directly into the patient's bloodstream. The invention provides for the safe introduction of the needle and catheter into a patient, yet it is a relatively simple device that allows for inexpensive packaging.

Prior to use, the safety catheter is kept sterile by a seal 26, as shown being removed from
10 the device in Figure 2. The seal 26 defines a closed space within a housing 40 of a needle retraction chamber 14 around a needle 24 and catheter 12. Thus, the needle 24 and catheter 12 may be kept sterile prior to use. Preferably, the seal 26 is made of paper or plastic as is conventional in the packaging of medical products, and is attached to the housing 40 with adhesive. Alternatively, the seal may be rigid and may snap on and off the housing 40 of the
15 needle retraction chamber 14.

With particular reference to Figure 3, the safety catheter 10 comprises a needle hub assembly 22 contained within the housing 40 of the needle retraction chamber 14, a needle 24 attached to the needle hub assembly 22, and a catheter 12 removably attached to the needle hub assembly 22 and the needle 24. The housing 40 of the needle retraction chamber 14 has an interior
20 cavity 16, a distal end 18, and a proximal end 20.

The catheter 12 is shown in Figure 3 prior to use. It is positioned on top of the needle hub assembly 22 and the needle 24 so that only the tip of the needle 24 protrudes from the catheter 12. This configuration allows the needle 24 and catheter 12 to be inserted simultaneously in a patient. The needle 24 may then be removed, leaving the catheter 12 partially inserted in the
25 patient. Alternatively, a catheter may be contained within the needle.

The needle hub assembly 22 is movable with respect to the housing 40 of the needle

5 retraction chamber 14. In particular, the needle hub assembly 22 is movable between the proximal end 20 and the distal end 18 of the housing 40. Also, the needle hub assembly 22 may be latched in a retracted or extended position as described in the embodiments set forth below.

With continued reference to Figure 3, the safety catheter includes the above-recited features, but the housing 40 of the needle retraction chamber 14 has a slot 28 extending along its
10 longitudinal axis, and the needle hub assembly 22 is at least partially accessible through the slot 28. The needle hub assembly 22 is prevented from passing out the distal end 18 of the housing 40 of the needle retraction chamber 14 by a rigid shelf 30 attached to the distal end 18 of the interior cavity 16 of the housing 40. The safety catheter 10 may also include a thumb-tab 38, rigidly attached to, or integral with the needle hub assembly 22. The thumb-tab 38 extends from the
15 interior cavity 16 of the housing 40 through the slot 28 of the housing 40, and facilitates movement of the needle hub assembly 22 with respect to the housing 40 of the needle retraction chamber 14.

In one embodiment, illustrated in Figures 3-6, the safety catheter 10 comprises a latching mechanism to alternatively secure the needle hub assembly 22 in either a retracted or extended
20 position. The latching mechanism comprises at least one distal recess 32 in the housing 40 of the needle retraction chamber 14, at least one proximal recess 34 in the housing 40 of the needle retraction chamber 14, and at least one nub 36 attached to the needle hub assembly 22. The nub 36 is capable of alternative engagement with the distal and proximal recesses, 32 and 34, respectively. Figure 3 shows the safety catheter 10 in a retracted position prior to use. The nubs
25 36 are engaged in the proximal recesses 34, thus securing the needle hub assembly 22 in a retracted position.

5 In Figure 4, the safety catheter 10 is shown deployed, the nubs 36 are engaged in the distal recesses 32, securing the needle hub assembly 22 in an extended position. In this configuration, the needle 24 and catheter 12 are securely extended from the housing 14, and are ready for insertion in a patient. Figure 6 shows a cross sectional view of the nubs 36 engaged in the distal recesses 32.

10 Figure 5 shows the safety catheter 10 after insertion of the needle 24 and catheter 12 into a patient and after subsequent retraction of the needle hub assembly 22 and attached needle 24 into the housing 14. The nubs 36 are engaged in the proximal recesses 34, and the catheter 12 is freed and is left partially inserted into a patient.

 In another embodiment, illustrated in Figures 7-9, the safety catheter 110 includes a
15 second latching mechanism to hold the needle hub assembly 122 in a retracted or extended position. The latching mechanism comprises a distal opening 132 in the housing 140 of the needle retraction chamber 114, a proximal opening 134 in the housing 140 of the needle retraction chamber 114, and a spring-biased protrusion 136 attached to the needle hub assembly 122 for engagement in the distal and proximal openings, 132 and 134, respectively.

20 Figure 7 shows the safety catheter 110 in a retracted position prior to use. The spring-biased protrusion 136 is engaged in the proximal opening 134, thus securing the needle hub assembly 122 in a retracted position. The needle 124 and catheter 112 are entirely contained within the housing 140.

 The safety catheter 110 is shown deployed in Figure 8. The spring-biased protrusion 136
25 is engaged in the distal opening 132, thus securing the needle hub assembly 122 in an extended position. The needle 124 and catheter 112 are securely extended from the housing 140, ready for

5 insertion in a patient. Figure 8 also shows the retraction of the needle 124 and needle hub assembly 122 into the housing 140 of the needle retraction chamber 114 via the thumb-tab 138.

Figure 9 shows the safety catheter 110 following insertion of the needle 124 and the catheter 112 into a patient and after the subsequent retraction of the needle hub assembly 122 and the attached needle 124. The spring-biased protrusion 136 is engaged in the proximal opening 134
10 in the housing 140 of the needle retraction chamber 114, thus securing the needle hub assembly 122 in a retracted position. The catheter 112 is freed from the safety catheter 110, and is partially inserted into a patient.

From the foregoing it can be appreciated that the present invention overcomes many of the limitations of the existing art. The present invention provides a safety catheter with a needle
15 retraction chamber doubling as the needle cover, thus the need for a separate needle cover is eliminated. Moreover, the needle and catheter of the safety catheter may be kept sterile through the use of a simple seal, therefore the relatively elaborate packaging required in the prior art is simplified.

The present invention may be embodied in other specific forms without departing from its
20 spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

25

- 5 1. A sealable safety catheter assembly having a combination needle retraction chamber and
cover, comprising:
- a needle retraction chamber having a housing with an interior cavity and a distal and
proximal end;
- a needle hub assembly disposed within said housing, wherein said needle hub assembly is
10 movable with respect to said housing;
- means for alternatively positioning said needle hub assembly in a retracted or extended
position;
- a needle attached to said needle hub assembly such that said needle is movable from a
retracted position to an extended position;
- 15 a catheter removably attached to said needle hub assembly and said needle; and
- a seal removably attached to said needle retraction chamber such that an enclosed space is
defined within said needle retraction chamber about said needle and catheter when said needle is
in the retracted position.
- 20 2. The sealable safety catheter assembly of claim 1 wherein said seal is a rigid cap capable of
snapping on and off said needle retraction chamber.
3. The sealable safety catheter assembly of claim 1 wherein said seal is attached to said
needle retraction chamber with adhesive.
- 25 4. The sealable safety catheter assembly of claim 3 wherein said seal is plastic.

- 5 5. The sealable safety catheter assembly of claim 3 wherein said seal is paper.
6. The sealable safety catheter assembly of claim 1 wherein said catheter does not exceed 3 inches in length.
- 10 7. A sealable safety catheter assembly having a combination needle retraction chamber and cover, comprising:
- a needle retraction chamber having a housing with an interior cavity and a distal and proximal end, and also having a slot extending along the longitudinal axis of said housing;
- a needle hub assembly disposed within said housing, wherein said needle hub assembly is
- 15 movable with respect to said housing, and at least a portion of said needle hub assembly is accessible through said slot;
- means for alternatively latching said needle hub assembly in a retracted or extended position;
- a needle attached to said needle hub assembly such that said needle is movable from a
- 20 retracted position to an extended position;
- a catheter removably attached to said needle hub assembly and said needle; and
- a seal removably attached to said needle retraction chamber such that an enclosed space is defined within said needle retraction chamber about said needle and catheter when said needle is
- in the retracted position.
- 25
8. The sealable safety catheter assembly of claim 7, further comprising a shelf rigidly secured

5 to the interior cavity at the distal end of said housing, whereby said shelf prevents said needle hub assembly from passing out said distal end of said housing.

9. The sealable safety catheter assembly of claim 7, wherein said means for alternatively
latching includes at least one nub secured to said needle hub assembly, and at least one recess at
10 both the distal and proximal ends of said housing, positioned such that the nub(s) may be
alternatively engaged in the distal or proximal recesses, causing the needle hub assembly to be
secured in a retracted or extended position.

10. The sealable safety catheter assembly of claim 7, wherein said means for alternatively
15 latching includes openings in the distal and proximal ends of said housing and a spring-biased
protrusion on said needle hub assembly, such that the spring-biased protrusion may be
alternatively engaged in the distal or the proximal opening, causing the needle hub assembly to be
secured in a retracted or extended position, and wherein said seal also covers said distal and
proximal openings prior to use.

20

11. The sealable safety catheter assembly of claim 7 wherein said seal is a rigid cap capable of
snapping on and off said needle retraction chamber.

12. The sealable safety catheter assembly of claim 7 wherein said seal is attached to said
25 needle retraction chamber with adhesive.

- 5 13. The sealable safety catheter assembly of claim 12 wherein said seal is plastic.
14. The sealable safety catheter assembly of claim 12 wherein said seal is paper.
15. The sealable safety catheter of claim 7, further comprising a thumb-tab rigidly attached to
10 said needle hub assembly such that said thumb-tab extends from the interior cavity of said housing
through the slot of said housing, and facilitates the movement of said needle hub assembly with
respect to said housing.
16. The sealable safety catheter assembly of claim 7 wherein said catheter does not exceed 3
15 inches in length.
17. A sealable safety catheter assembly having a combination needle retraction chamber and
cover, comprising:
- 20 a needle retraction chamber having a housing with an interior cavity and a distal and
proximal end, and also having a slot extending along its longitudinal axis;
- a needle hub assembly disposed within said housing, wherein said needle hub assembly is
movable with respect to said housing;
- a thumb-tab rigidly attached to said needle hub assembly, such that said thumb-tab extends
from the interior cavity of said housing through the slot of said housing, and facilitates the
25 movement of said needle hub assembly with respect to said housing;
- means for alternatively latching said needle hub assembly in a retracted or extended

5 position;

a needle attached to said needle hub assembly such that said needle is movable from a retracted position to an extended position;

a catheter not exceeding 3 inches in length removably attached to said needle hub assembly and said needle; and

10 a seal removably attached to said needle retraction chamber such that an enclosed space is defined within said needle retraction chamber about said needle and catheter when said needle is in the retracted position.

18. The sealable safety catheter assembly of claim 17, further comprising a shelf rigidly
15 secured to the interior cavity at the distal end of said housing, whereby said shelf prevents said needle hub assembly from passing out said distal end of said housing.

19. The sealable safety catheter assembly of claim 17 wherein said seal is a rigid cap capable of snapping on and off said needle retraction chamber.

20

20. The sealable safety catheter assembly of claim 17 wherein said seal is attached to said needle retraction chamber with adhesive.

21. The sealable safety catheter assembly of claim 20 wherein said seal is plastic.

25

22. The sealable safety catheter assembly of claim 20 wherein said seal is paper.

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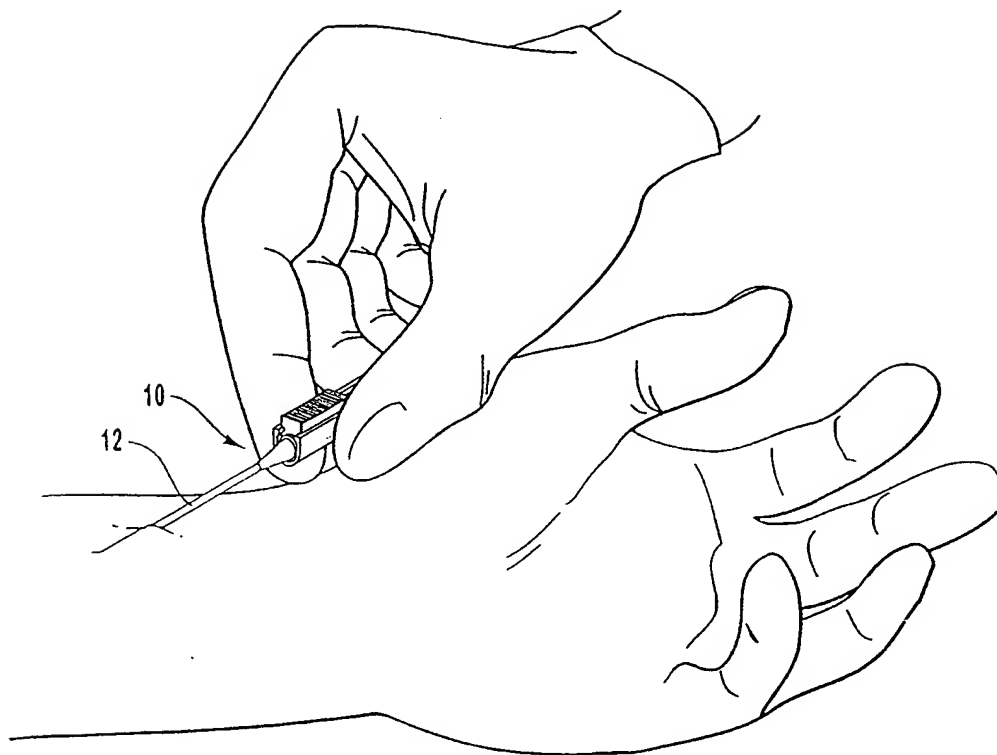


FIG. 1

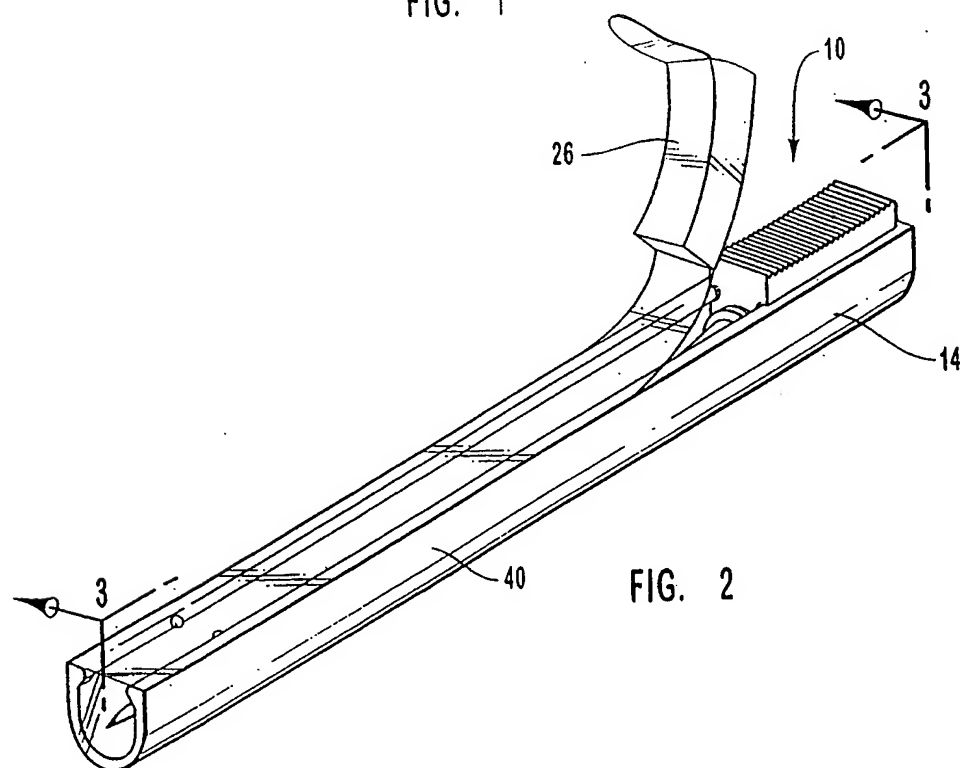


FIG. 2

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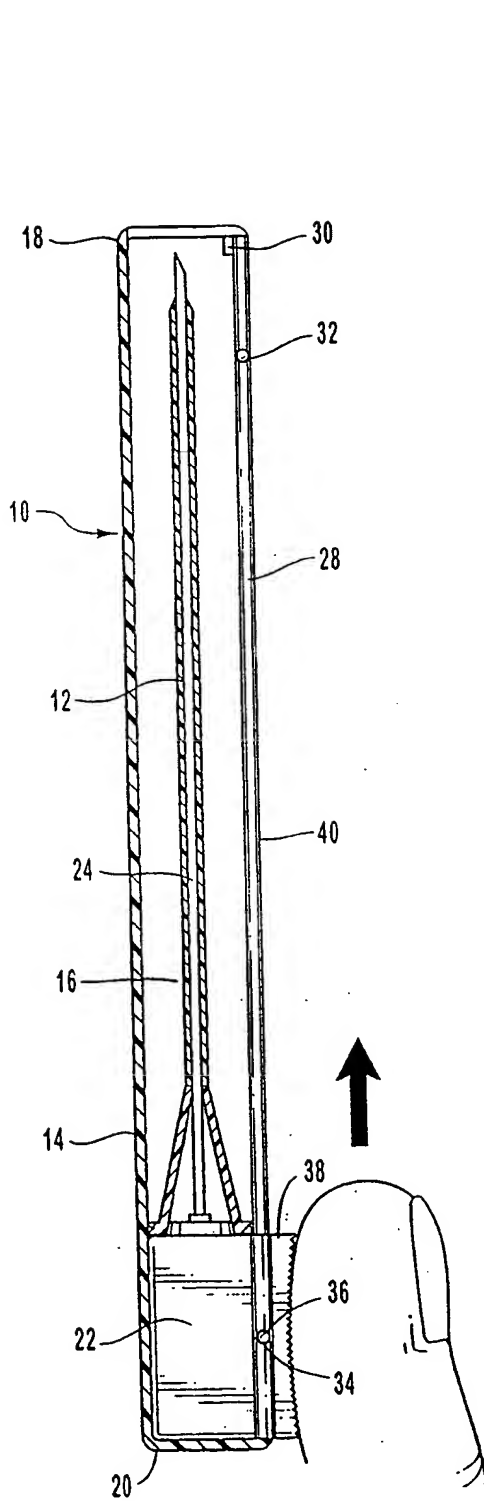


FIG. 3

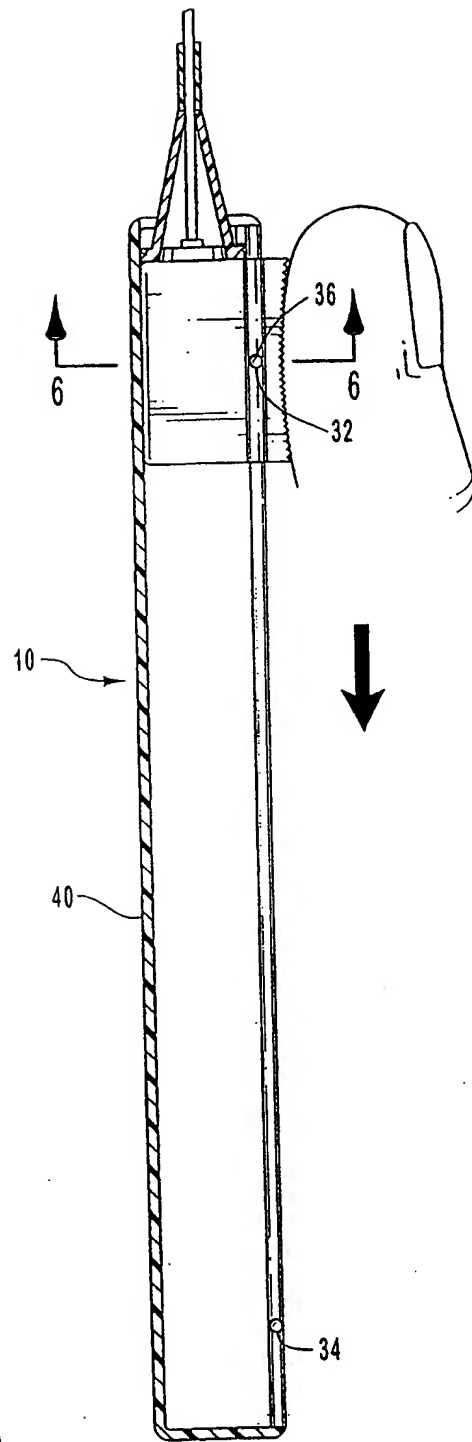


FIG. 4

3 / 5

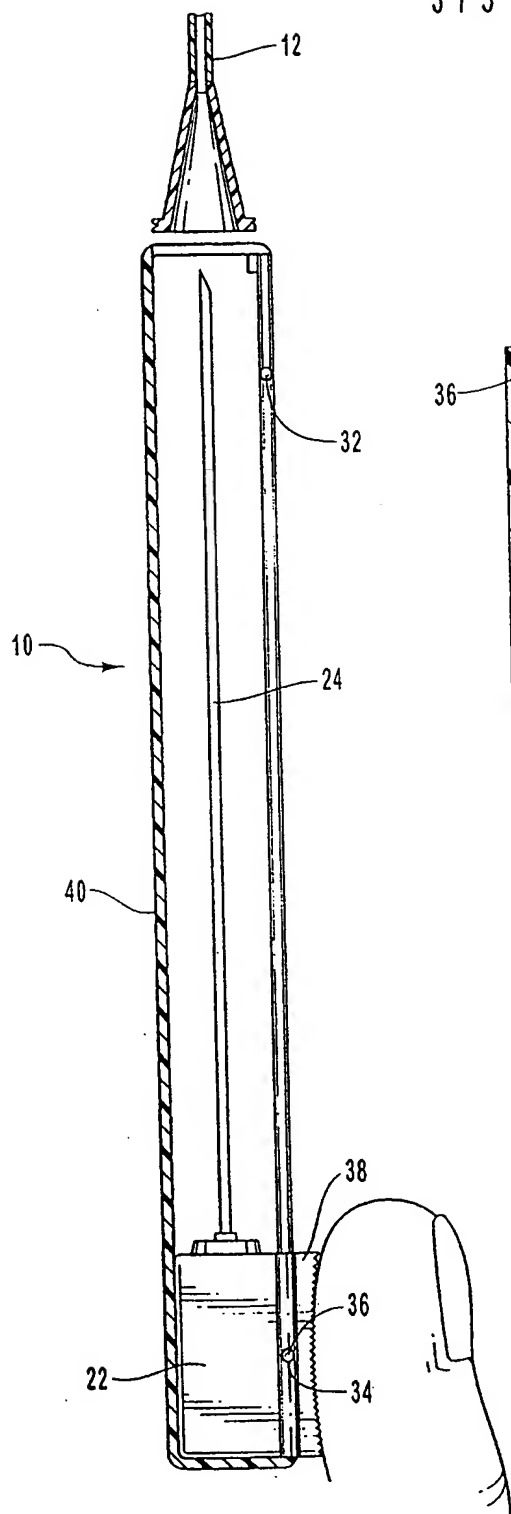


FIG. 5

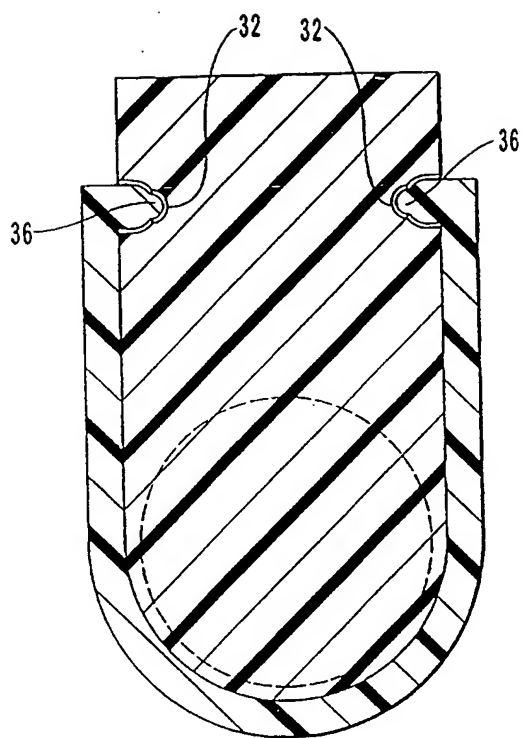


FIG. 6

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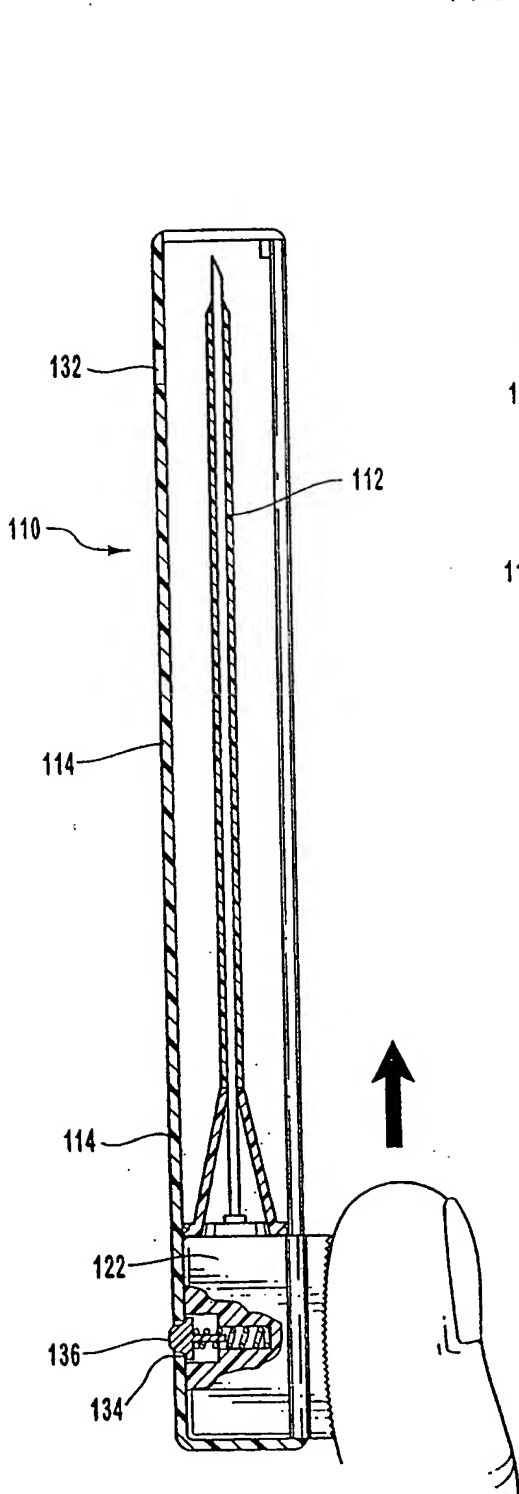


FIG. 7

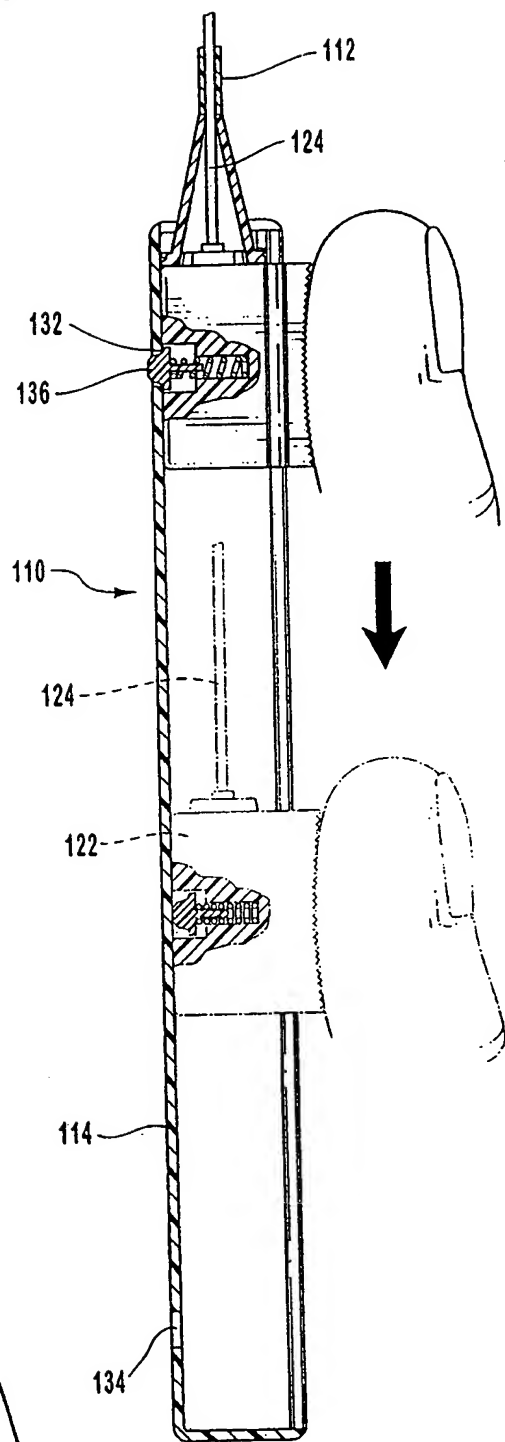


FIG. 8

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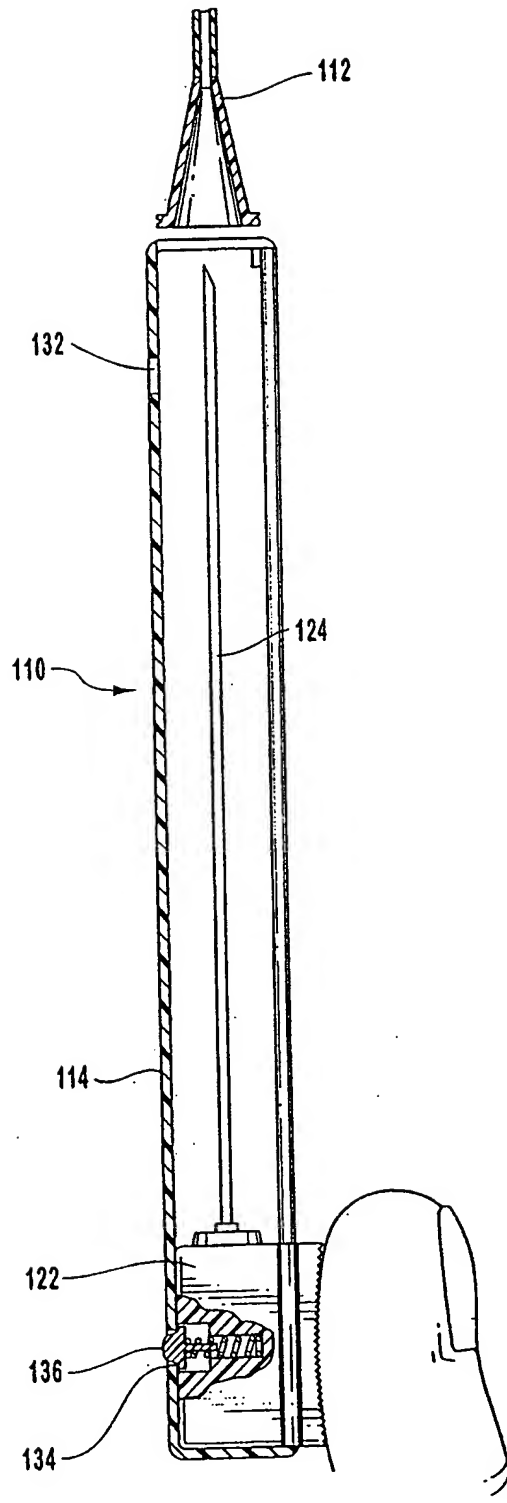


FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/14472

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M25/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 176 650 A (HAINING MICHAEL L) 5 January 1993 (1993-01-05) column 2, line 35 -column 3, line 53; figures	1,2,6-9, 11,15-19
A	EP 0 599 564 A (BOC OHMEDA AB) 1 June 1994 (1994-06-01) the whole document	1,7,15, 17
A	EP 0 815 887 A (TOGO MEDIKIT CO LTD) 7 January 1998 (1998-01-07) abstract; figures	1,7,17
A	US 4 850 961 A (WANDERER ALAN A ET AL) 25 July 1989 (1989-07-25) claim 1	1,7,15, 17
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No
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